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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al. EX REL. JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, v. JANSSEN PRODUCTS, LP, Defendant.	Case No. 12-7758 (ZNQ)(JBD)

RELATORS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION FOR A NEW TRIAL

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Relators Jessica Penelow and Christine Brancaccio ("Relators") hereby oppose Defendant Janssen Products, LP's ("Janssen") Motion for a New Trial, filed on August 12, 2024. Dkt. 474. For the reasons stated below, Janssen's Motion should be denied in its entirety.

INTRODUCTION

After nearly twelve years of litigation and a jury trial, resulting in a verdict finding that Janssen's fraudulent off-label ("OL") marketing scheme caused more than $150 million in damages to federal and state governments, Janssen persists with its arguments that Relators failed to prove virtually anything. Attacking Relators' evidence, the Court's instructions, the verdict sheet, and the unanimous jury verdict, Janssen asks the Court to order a new trial.

The jury reached its verdict after a trial spanning from May 6 to June 13, 2024, during which Relators' counsel presented a mountain of evidence that included direct and cross-examination of 30 witnesses (including 19 current or former Janssen employees and 6 expert witnesses) and hundreds of Janssen's own documents. But despite the voluminous substantive evidence presented by Relators at trial, Janssen now argues that Relators failed to present evidence to prove three of the four elements of their FCA claims: causation, materiality, and falsity; that three jury instructions were erroneous; and that the jury "abandoned a review of the trial

evidence" and reached a verdict that "has no connection at all with the evidence presented in this case." Def. Br. at 1.[1] Janssen's Motion should be denied.

GOVERNING LEGAL STANDARDS

Under Third Circuit law, a district court may grant a new trial under Fed. R. Civ. P. 59 where "the verdict is against the clear weight of the evidence; damages are excessive; the trial was unfair; [or] substantial errors were made in the admission or rejection of evidence or the giving or refusal of instructions." *Lightning Lube, Inc. v. Witco Corp.*, 802 F. Supp. 1180, 1186 (D.N.J. 1992) (citations omitted), *aff'd*, 4 F.3d 1153 (3d Cir. 1993). When reviewing a motion for a new trial, the court must "'view all the evidence and inferences reasonably drawn therefrom *in the light most favorable to the party with the verdict*.'" *Wagner v. Firestone Tire & Rubber Co.*, 890 F.2d 652, 656 (3d Cir. 1989) (emphasis added); *Liger6, LLC v. Antonio*, No. CV 13-4694 (JLL), 2019 WL 1487243, at *3 (D.N.J. Apr. 3, 2019) ("When reviewing a motion for a new trial, a court must view the evidence *in the light most favorable to the party for whom the verdict was returned*.") (emphasis added).[2]

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[1] "Def. Br" refers to Janssen's accompanying Memorandum of Law, at Dkt. 474-1.

[2] Janssen cites inapposite out-of-district caselaw to argue that the Court "need not view the evidence in the light most favorable to the verdict winner." Def. Br. at 16 (citing *Valentin v. Crozer-Chester Med. Ctr.*, 986 F. Supp. 292, 298 (E.D. Pa. 1997)). This standard is incorrect, as *Liger6* confirms under *Wagner*.

Where a motion for a new trial is based primarily on the weight of the evidence, the discretion of the trial court is limited. *See Klein v. Hollings*, 992 F.2d 1285, 1290 (3d Cir. 1993). Indeed, "new trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks [the] conscience." *Williamson v. Consol. Rail Corp.,* 926 F. 2d 1344, 1353 (3d Cir. 1991); *see also Greenleaf v. Garlock, Inc.*, 174 F.3d 352, 366 (3d Cir. 1999). A motion for new trial due to an erroneous instruction should be granted only if the instruction "fails to fairly and adequately present the issues in the case without confusing or misleading the jury." *Donlin v. Philips Lighting N. Am. Corp.*, 581 F.3d 73, 79 (3d Cir. 2009) (citations and internal quotations omitted).

ARGUMENT

I. RELATORS PROVED THE ELEMENTS OF THEIR FCA CLAIM THROUGH SUBSTANTIAL EVIDENCE

Rehashing most of the same arguments it advances in its Motion for Judgment as a Matter of Law under Rule 50(b),[3] Janssen first argues that "Relators failed to

[3] For the sake of brevity and economy, Relators incorporate herein the entirety of the arguments and evidence set forth in their Opposition to Janssen's Motion for Judgment as a Matter of Law, which is being simultaneously submitted herewith (referred to herein as "Rel. Br. Rule 50(b)"). As used herein, "Def. Br. Rule 50(b)" refers to Janssen's Memorandum of Law in Support of Motion for Judgment as a Matter of Law, Dkt. 473-1. "Def. Br." refers to Janssen's Memorandum of Law in Support of Motion for New Trial, Dkt. 474-1.

present any evidence necessary to sustain at least three elements" of their claim—causation, materiality, and falsity. Def. Br. at 17–26. This attack fails in its entirety.

A. Relators proved causation.

Janssen argues that Relators failed to prove causation. Def. Br. at 17–19. This is substantially the same argument that Janssen raised in its Rule 50(b) motion. *See* Def. Br. Rule 50(b) at 8, which Relators fully responded to and refuted in their opposition thereto. *See* Rel. Br. Rule 50(b) at 4–18. The Court should deny Janssen's motion for new trial on this ground for the same reasons.

B. Relators proved materiality.

Janssen next argues that Relators failed to prove materiality. Def. Br. pp. 20–23. This is substantially the same argument that Janssen raised in its Rule 50(b) motion, Def. Br. Rule 50(b) at 17, which Relators fully responded to and refuted. *See* Rel. Br. Rule 50(b) at 18–28. The Court should deny Janssen's motion for new trial on this ground for the same reasons.

C. Relators proved falsity.

Janssen next argues that Relators failed to prove falsity. Def. Br. pp. 23-26. This is substantially the same argument that Janssen raised in its Rule 50(b) motion, Def. Br. Rule 50(b) at 23, which Relators fully responded to and refuted. *See* Rel. Br. Rule 50(b) at 29–49. The Court should deny Janssen's motion for new trial on this ground for the same reasons.

II. THE COURT'S JURY INSTRUCTIONS WERE PROPER

Janssen next contends that three instructions in the Court's charge to the jury were erroneous and entitle it to a new trial. Def. Br. at 26–35. A district court "has broad discretion in fashioning a jury charge as long as it communicates 'the substance of the law' so the jury is not misled or confused." *United States v. Petersen*, 622 F.3d 196, 203 (3d Cir. 2010) (citing *United States v. McGill,* 964 F.2d 222, 235 (3d Cir. 1992)). None of the instructions were erroneous, and none entitle Janssen to a new trial.

A. Instruction No. 23 was correct.

Instruction No. 23, "State Law Claims," was correct in every respect. The Court properly instructed the jury that the States' False Claims Acts have similar or identical provisions to the federal False Claims Act ("FCA"). *See* Dkt. 424-1 at 78–90 (Parties' Jointly Proposed Jury Instructions).[4] The Court also instructed the jury on two express conditions of payment for Medicare Part D, Medicaid, and ADAP in a separate instruction. *See* Dkt. 424-11 at 25 (Instruction No. 17, "Overview of

[4] Janssen cannot contest this fact: its proposed jury instructions on the *elements* of the "State Law Claims" were the same as Relators' proposed instructions. *Compare* Relators' proposed instruction, *id*. at 78 ("Most States' False Claims Acts are modeled on the federal False Claims Act and have very similar or identical provisions . . . . except I will provide separate instructions for Texas."), *with* Janssen's proposed instruction, *id*. at 79 ("Most States' False Claims Acts are modeled on the federal False Claims Act and have very similar or identical provisions, except for Texas, on which I will instruct you separately.").

Relators' Claims") (providing that these "federal health care programs, including Medicare Part D, Medicaid, and ADAP" (1) will cover and pay for a drug used for a "medically accepted indication," and (2) coverage for drugs may be excluded if they are not medically "reasonable and necessary").[5] Moreover, Relators proved through overwhelming evidence at trial that compliance with FDA law prohibiting false and misleading OL marketing is itself a condition of reimbursement for *all* government payors in this case—separate and apart from expressly designated conditions of payment for Medicare, Medicaid, and ADAP. *See* Rel. Br. Rule 50(b) at 30–34. The jury specifically found in its verdict that Janssen violated the False Claims Act by "*unlawfully promoting*" Prezista or Intelence.

Because the same standards and the same FCA elements applied to all three payors, the Court correctly instructed the jury that if it found Janssen liable or *not* liable under the federal FCA (for Medicare and ADAP) it should find the same way for the States' FCAs (for Medicaid). *See* Dkt. 424-11 at 42 (Instruction No. 23 "State

[5] Relators provided substantial authority for this proposed instruction, including this Court's prior opinion denying Janssen's motion to dismiss. *See* Dkt. 424-1 at 38–39 (Parties' Jointly Proposed Jury Instructions); *see also United States ex rel. Penelow v. Johnson & Johnson, et al.*, No. CV127758MASLHG, 2017 WL 2367050, *4 (D.N.J. May 31, 2017) (Shipp, J.) (holding that "Relators can adequately plead a false claim with respect to Prezista and Intelence" as to both Medicare and Medicaid if the drugs were not medically "reasonable and necessary"); *see also* Rel. Br. Rule 50(b) at 42–48, 50–56.

Law Claims"). As Janssen itself argues in its Rule 50(b) motion, federal and state FCA claims "*succeed or fail together*" where "no party has alleged a material difference between the *standards applicable to the FCA and equivalent state laws*." Def. Br. Rule 50(b) at 42 (citing *United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 543 n.159 (E.D. Pa. 2022)) (emphasis added). There is no difference between the federal and state FCA standards here.

Nonetheless, Janssen appears to argue now that the express conditions for reimbursement for the States' Medicaid programs and ADAP *may* differ from Medicare,[6] and, therefore, whether claims submitted to those payors were false under the state and federal FCAs *may* differ. Def. Br. at 28.[7] This argument fails for multiple reasons.

First, Janssen does not challenge Instruction No. 17 (instructing the jury to consider two express conditions of payment for all three "federal health care programs") or any of the instructions relating to the federal FCA elements in its

[6] Janssen again improperly lumps ADAP, a federally funded grant program, together with its state Medicaid arguments for the "State Law Claims" instruction. *See* Rel. Br. Opp. 50(b) at 40 n.39; *see* Dkt. 424-11 at 42–43 (Instruction No. 23, "State Law Claims") (addressing only *state Medicaid programs*, not ADAP).

[7] Whether Janssen is making this argument in its Motion for New Trial is entirely unclear. The Court instructed the jury to consider the same two conditions of payment for all three "federal health care programs" (Medicare, Medicaid, and ADAP) in Instruction No. 17, which is a correct instruction that Janssen does not even challenge in its Motion for New Trial.

Motion for New Trial. To the extent its attack on Instruction No. 23 is predicated on a separate or additional "erroneous" instruction, which Janssen failed to brief or even identify, Janssen's arguments are waived. *See Fagan v. Fischer*, No. CV147013FLWTJB, 2016 WL 347318, at *7 n.8 (D.N.J. Jan. 28, 2016) ("'It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work . . . .'").

Second, even if Janssen had actually raised a challenge to Instruction No. 17 separate from, or in addition to, Instruction No. 23, Janssen fails to explain how Instruction No. 17 is erroneous or how it makes Instruction No. 23 erroneous. Instead, it argues, in only two sentences, that state Medicaid programs "*may*, but do not necessarily," follow federal law, and that trial testimony from two fact witnesses purportedly "confirmed that state Medicaid programs differ widely" in their coverage requirements. Def. Br. at 28 (emphasis in original). It further argues in one sentence (incorrectly) that ADAP "does not restrict uses of HIV drugs."[8] *Id*.

Again, ADAP, as a federally funded program, is not even *referenced* in Instruction No. 23 ("State Law Claims") (addressing only "Medicaid programs"), which Janssen challenges here. As to Medicaid, Janssen cites to a federal statute providing that state Medicaid programs may exclude coverage of a "covered

[8] ADAP will not cover drugs that are not for a "medically accepted indication" or are "medically unnecessary." *See* Rel. Br. Rule 50(b) at 54 n.45.

outpatient drug" if the prescribed use is not for a "medically accepted indication." *Id*. (citing 42 U.S.C. § 1396r-8(d)(1)(B)(i)). Janssen does not explain how that statute conflicts with the Court's Instruction No. 17 at all or how it demonstrates that Instruction No. 23 is erroneous.

In short, any complaint that Janssen has with the Court's Instruction No. 23 (or any other instruction implicated by Instruction No. 23 that Janssen did not raise in its Motion) is the product of Janssen's own tactics, which it employed throughout trial and continues to employ in its Motion as to Relators' state Medicaid and ADAP claims. As the Court will note, Janssen intentionally and repeatedly failed to identify for the Court the express coverage conditions of the 26 States' Medicaid programs or of ADAP that it contends actually *are* substantively different from the "medically accepted indication" or medically "necessary and reasonable" conditions, which the Court provided in Instruction No. 17 as to Medicare, Medicaid, and ADAP.

Instead, Janssen carried forward its Rule 12(b)(6) *pleading* arguments as to the Medicaid and ADAP claims—that Relators had not alleged the express coverage conditions for its "state law" claims—and continually argued before and during trial that it was Relators' "burden" to provide "evidence" or to "show" what those conditions are. Janssen did so in the Final Pretrial Order,[9] its proposed final

[9] "Relators have not *produced any evidence* of what constitutes a "false" claim under each state's respective law." Dkt. 315 at 84 n.9 (Final Pretrial Order) (emphasis added).

instructions,[10] in argument regarding the Court's instructions before closing,[11] and now, again, in its Motion for New Trial.[12]

However, this was ***a jury trial***, not a Rule 12(b)(6) motion to dismiss. Janssen lost its pretrial challenges to Relators' state Medicaid and ADAP claims[13] and they were presented for determination by a jury. And at ***trial***, a district court's instructions to the jury—including expressly designated coverage requirements for healthcare programs—is not a pleading requirement subject to a motion to dismiss. The

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[10] *See* Dkt. 424-1 at 39–40 (Jointly Proposed Final Instructions) ("Janssen's Proposal") ("The coverage requirements of each state Medicaid program are in the discretion of the respective states, and it is *Relators' burden to establish what those requirements are* or face *dismissal of their claims*, as other courts have held.") (citing *United States ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 295 (D. Mass. 2012) (dismissing relator's state-law claims under Rule 12(b)(6) for failing to *plead* allegations relating to state Medicaid coverage requirements in its complaint)) (emphasis added).

[11] 6/11/24 Tr. 7880:04–13 ("Medicaid and ADAP are not subject, *or at least are not required*, to follow the medically accepted indication provision of the Medicare law. So it would be incorrect as a matter of law to instruct the jury that the coverage requirements are the same, and I would submit that *the burden is on the Relators to show what the coverage requirements for those other entities are*.") (addressing now-Instruction No. 17) (emphasis added).

[12] "State Medicaid programs *may*, but do not necessarily, follow the requirements of federal law. . . . Relators thus needed to offer at least some proof or some instruction on the content of the relevant state laws or coverage requirements to support their case—but chose instead to offer *no* proof of the content of any state coverage requirements, much less any facts relevant to the application of such requirements." Def. Br. at 28 (emphasis in original).

[13] *See supra*, n.5.

substance of a proper instruction from the Court to the jury on express conditions of payment for Medicaid or ADAP was not Relators' "burden" to "show" or "prove."

Rather, if Janssen had objections to the Court's Instruction No. 23 *or any other* because it believed the States' Medicaid programs or ADAP have or *may* have different coverage requirements from Medicare,[14] it was obligated to make a specific, cogent objection *identifying those requirements* and demonstrating how they actually differ from the Court's instructions to the jury on the express conditions of reimbursement for all three programs identified in Instruction No. 17.[15] But Janssen never informed the Court before the jury's verdict what it contends the proper instruction for the state Medicaid or ADAP coverage requirements actually *is*, and it still has not done so in its Motion for New Trial.

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[14] They do not. *See* Rel. Br. Rule 50(b) at 53–54.

[15] "[A]n objection must be both cogent and specific to the alleged error." *Lesende v. Borrero*, 752 F.3d 324, 335 (3d Cir. 2014) (requiring an objection to distinctly state its grounds because "[a]ny circumstance that leaves district judges responsible for the resolution of inarticulate, incomprehensible, or otherwise unsupported objections is untenable"); *see DeCaro v. Hasbro, Inc.*, 580 F.3d 55, 60 (1st Cir. 2009) ("An objection to an instruction on the ground that it 'simply overstates the law,' or that it should have been worded differently, was insufficient because it failed to convey with proper specificity what the judge had done wrong and what he should have done to remedy the ostensible harm."); *see Chem. Leaman Tank Lines, Inc. v. Aetna Cas. & Sur. Co.*, 89 F.3d 976, 993 (3d Cir. 1996) (holding an objection failed to comply with Rule 51 where it "did not specify the authority upon which it was based"); *Porter v. City of Philadelphia*, 337 F. Supp. 3d 530, 559 (E.D. Pa. 2018), *rev'd on other grounds*, 975 F.3d 374 (3d Cir. 2020) (holding an objection did not comply with Rule 51 where it was "consistently vague" and "counsel never cited any authority for its position" or "broke down its argument").

An objection to the Court's allegedly "erroneous" instructions to the jury cannot be predicated on Janssen's argument that state Medicaid or ADAP coverage requirements *may* be different. The Court provided proposed instructions to the jury, and it is the objecting party's burden to timely provide a *cogent* objection specifically explaining *why* the proposed objection is improper. Relators are not the party attacking the Court's instructions to the jury; *Janssen is*.

Because Janssen failed to properly object to the Court's instructions by identifying material differences between the Court's "medically accepted indication" or medically necessary instruction and the coverage requirements under the States' Medicaid programs and ADAP, it *waived* any objection to the Court's instructions on those grounds—and the Court should so find.[16] Janssen cannot revive waived objections to instructions about Medicaid or ADAP coverage requirements in its Motion for New Trial.[17]

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[16] *See Dunn v. HOVIC*, 1 F.3d 1371, 1379 (3d Cir.), *modified*, 13 F.3d 58 (3d Cir. 1993) (holding a "general objection" that the requested jury instruction does not provide the correct legal standard is "not specific enough to inform the court how to provide clearer standards" and is therefore waived under Rule 51) (citing *Robertson Oil Co. v. Phillips Petroleum Co,*, 930 F.2d 1342 (8th Cir. 1991)); *see also Robertson*, 930 F.2d at 1347 (holding a "general objection" that an instruction violated the Constitution without "elaborat[ing] any further on the [correct legal] standard" does not comply with Rule 51).

[17] *See Ghee v. Marten Transp., Ltd.*, 570 F. App'x 228, 231 (3d Cir. 2014) (holding a "request for a new trial could not have rested on an objection that the defendants wholly failed to lodge"); *see also Waldorf v. Shuta*, 142 F.3d 601, 629 (3d Cir.1998)

At any rate, the Court's Instruction No. 17 is substantially correct as to both state Medicaid *and* ADAP requirements.[18] Even if Janssen had not waived its objections to the Court's instructions for failing to make timely, cogent, specific objections, its arguments would still fail.

Finally, the Court properly instructed the jury that "a claim made to a federal health care program is false if it seeks reimbursement for a prescription that is not eligible for reimbursement." *See* Dkt. 424-11 at 34, (Instruction No. 19.1, "Falsity"). Janssen does not contend that this instruction relating to "Falsity" under the FCA is erroneous. Relators proved, aside from any expressly designated conditions of payment, that compliance with FDA law against false and misleading OL marketing is *itself* a condition of payment for all three government payors, and Janssen therefore caused the submission of false claims to Medicare, Medicaid, and ADAP that were not eligible for reimbursement. *See* Rel. Br. Rule 50(b) at 30–48, 50–56. Therefore, any purported error in the jury instructions relating to express conditions

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(holding "a party who fails to object to errors at trial waives the right to complain about them following trial").

[18] *See* Rel. Br. Rule 50(b), at 53–54 (ADAP requires covered drug to be for a "medically accepted indication" and "medically necessary"); (the States' Medicaid programs at issue in this case require prescription drugs to be "medically necessary"); *see also U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016) ("Federal reimbursement for prescription drugs under Medicare and Medicaid is generally limited to drugs prescribed for FDA-approved (on-label) uses or for certain purposes included in any of three drug compendia.").

of payment for those same programs in Instruction No. 17 (which Janssen has even not challenged in its Motion for New Trial) were harmless because Instruction No. 23 was unaffected.[19] Janssen's Motion for New Trial on this ground fails.

B. Instruction No. 26 was correct.

Janssen next argues that Instruction No. 26 did not inform the jury of the correct legal standard for damages in an FCA case, which Janssen asserts is the "benefit of the bargain" standard. Def. Br. at 29–32. This argument misstates the proper measure of damages in FCA cases regarding OL marketing of prescription drugs provided to patients that are reimbursed by government payors and ignores the evidence at trial. Janssen made substantially the same argument in its Rule 50(b) motion, Def. Br. Rule 50(b) at 43–46, which Relators fully responded to and refuted. Rel. Br. Rule 50(b) at 56–59. The Court should deny Janssen's motion for new trial on this ground for the same reasons.

Janssen further argues that, while the Court's Instruction No. 26 required the jury to differentiate damages between "state and federal claims," the verdict form did not break down false claims based on federal and state payors, such that the jury had no way to implement that instruction. Def. Br. at 30. That is also incorrect.

[19] *See O'Brien v. Middle E. F.*, 57 F.4th 110, 121–22 (3d Cir. 2023) (holding an erroneous instruction was "harmless" did not warrant a new trial because it "did not affect the outcome of the case").

The Court's instructions required the jury to "differentiate between damages suffered by the United States, the twenty-six states, and the District of Columbia." Dkt. 424-11 at 46 (Instruction No. 26, "Measure of Damages"). The jury found the damages sustained by "the United States" in Question Three ($120,004,736.00) and the damages sustained by "the States" (including the District of Columbia) in Question Eight ($30,001,184.00). *See* Dkt. 435 at 3, 6 (Jury Verdict). Damages to the United States were predicated on the jury's finding of liability as to the federal FCA in Question One. Damages to the States were predicated on the jury's finding of liability as to the States' FCAs in Question Seven. *See id.* at 3, 5–6. The jury thus differentiated damages between "state and federal claims." Nothing more was required, and Janssen's argument fails.

C. Instruction No. 22 was correct.

Janssen next argues that Instruction No. 22 was improper and requires a new trial. Janssen asserts that this instruction improperly resolved a factual issue in Relators' favor regarding falsity and scienter. More specifically, Janssen asserts that its compliance officer, Dr. Amit Patel, testified that it was common industry practice to assume that if the FDA, through its Division of Drug Marketing, Advertising, and Communications ("DDMAC"), does not object to a company's promotional material in writing, then those materials are effectively approved for use in the field. Janssen claims that this testimony supported its defenses to falsity and scienter. According

to Janssen, Instruction No. 22 "effectively erases" Dr. Patel's testimony and "improperly directed the jury to ignore" it. Def. Br. pp. 32–35. Janssen's assertions should be rejected.

Instruction No. 22 properly instructed the jury *on the law* regarding the FDA's approval process over promotional advertising. It reads as follows:

> You have heard testimony from a Janssen employee, Dr. Amit Patel, about the FDA's silence in response to certain of Janssen's promotional advertising submissions regarding Prezista and lipids. You also heard him testify that Janssen considered the FDA's silence in response to those advertising submissions as the FDA's indirect or tacit approval of Janssen's advertising.
>
> I am instructing you that there is no statute or regulation that says that the FDA's silence means that it has approved a promotional advertising submission.

Dkt. 424-11 at 41 (Instruction No. 22, "FDA Approval").

This instruction represents a correct statement of the law—albeit one that was less stringent than Relators requested. As Dr. Patel himself admitted during Relators' examination, FDA regulations and guidelines state that only the FDA's written communications may be considered "official." *See* 5/30/24 Tr. 4772:7–13 (Patel). Caselaw is abundantly clear that the FDA's silence does ***not*** indicate approval of a manufacturer's advertising. Janssen does not contend that the Court misstated the law.[20]

[20] Federal courts have repeatedly recognized that the FDA's silence is not evidence of approval. *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.,*

Nonetheless, Janssen claims that the Court's legally correct instruction "effectively erases" Dr. Patel's testimony from the jury's consideration. Def. Br. at 34. To the contrary, the instruction did not tell the jury to disregard Dr. Patel's testimony in any way. Dr. Patel was permitted to offer his testimony regarding

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No. 05-1699 CRB, 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006) ("Pfizer cites no authority for its assertion that the FDA's silence as to a particular advertisement means that the FDA 'necessarily determined' that the advertisement was not deceptive."); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 1836443, at *8 (N.D. Ill. May 8, 2017) ("AbbVie offers no support, and the Court is aware of none, for the proposition that the FDA's silence indicates its approval of the ad or similar ads."); *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 709 (9th Cir. 2016) ("*Nor can the FDA's silence be taken as tacit approval* such that Defendants were relieved from the duty to disclose the Rat Study when they chose to invoke "animal studies" as a grounds for their confidence in lorcaserin's approval.") (emphasis added); *Dean v. Colgate-Palmolive Co.*, No. EDCV 15-0107 JGB, 2015 WL 3999313, at *10 (C.D. Cal. June 17, 2015) ("To be sure, *the FDA may never have specifically prohibited those statements, but that does not equate to approval; in fact, the FDA may never have even examined the statements*.") (emphasis added); *Ault v. J.M. Smucker Co.*, No. 13 CIV. 3409 PAC, 2014 WL 1998235, at *3 (S.D.N.Y. May 15, 2014) ("In effect, Defendant interprets the FDA's lack of action as approval for Defendant's use of the phrase 'All Natural' to describe foods June 2, 2024 containing GMO. In reality, the FDA has stayed silent because it 'operates in a world of limited resources' where it 'must prioritize which issues to address.'") (internal citations omitted); *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Pracs. Litig.*, 701 F. Supp. 2d 356, 375 (E.D.N.Y. 2010) ("Defendant argues that the FDA's silence since the 2008 warning letters means that it has tacitly approved of the advertising, thereby preempting plaintiffs' state law false advertising claims. This is exactly the reasoning rejected in *Wyeth*."). Moreover, the FDA has issued regulations and guidelines stating that only its written responses shall be considered "official", and pharmaceutical companies shall not rely on any communications other than those that are in writing. *See* Dkt 394 at 4, Ex. 1 and 2.

Janssen's belief or understanding of industry practice surrounding the FDA's "indirect" or "effective" approval of Janssen's promotional messages. His testimony that Janssen believed its promotional messages were implicitly approved by the FDA's silence, despite the fact that the FDA never communicated any approval in writing, was not impacted in any way by the Court's instruction.[21] This testimony was not stricken by the Court, it remained in the record, and the jury heard all of it. The jury was free to give Dr. Patel's testimony its appropriate weight in light of applicable law.

Instruction No. 22 did not resolve a factual dispute in Relators' favor, as Janssen asserts here. It simply provided the jury with a correct statement of the law after a witness testified about that subject. Janssen's argument fails.

III. THE JURY'S AWARD OF DAMAGES IS APPROPRIATE AND SUPPORTED BY THE EVIDENCE

A. The evidence supports the assumptions made by Relators' damages experts.

Janssen argues that a new trial is required because Relators' data and damages experts used unsupported assumptions that render their testimony unreliable and inadmissible. Janssen refers to the purported assumptions that every sales call or speaker program conveyed an OL message, and that such OL messages influenced doctors' decisions to prescribe every time. Def. Br. pp. 36-38.

[21] *See* 5/30/24 Tr. 4841:10-4843:15, 4844:7-15.

This is the *third time* Janssen has posited these arguments aimed at Prof. Shaked and Ian Dew (first in its *Daubert* motion, and then again in its Motion to Strike these experts filed during trial), and this Court has already rejected these arguments on the prior two occasions. *See* Dkt. 294 at 31–37 (Mem. Op.); *see also* 6/10/24 Tr. 7748:16–7749:23, 7753:12–16. For the sake of judicial economy, Relators refer the Court to their prior Opposition to Janssen's Motion to Strike these experts, filed on June 11, 2024 (Dkt. 408), which is incorporated by reference here. For all the same reasons, and as the Court has already ruled before, the Court should reject Janssen's arguments in its motion for new trial.

B. The jury's verdict is not an improper "compromise."

Janssen next complains that the jury's damages award "is an improper compromise verdict" because the number of false claims and the damages the jury found "are untethered to any evidence presented at trial." Def. Br. at 38. A federal jury verdict that goes against a defendant, and which the defendant does not agree with, is not a "compromise verdict."

Rather, a "compromise verdict" is "*an award of suspiciously low damages* in a case of closely contested liability[.]" *Pryer v. C.O. 3 Slavic*, 251 F.3d 448, 457 n. 6 (3d Cir. 2001) (holding new trial should be granted where "the verdict most likely represented a compromise among jurors" on liability because the jury returned a $1.00 award after finding four out of six defendants liable for using excessive force

and plaintiff's injuries were uncontested) (*citing Morrison Knudsen Corp. v. Fireman's Fund Ins. Co.*, 175 F.3d 1221, 1255–56 (10th Cir. 1999) ("The most common example [of cases requiring retrial] is a compromise verdict, *i.e.*, an award of suspiciously low damages in a case of closely contested liability.") (emphasis added).[22] Janssen cites to both of these cases itself (Def. Br. at 39) but omits the relevant portions where the Third and Tenth Circuits define what a "compromise verdict" is.

Relators here do not complain of a damages award that is suspiciously low—they have moved for judgment on the jury's verdict. *See* Dkt. 475. Janssen itself contests the verdict because it is purportedly "excessive." Def. Br. at 35. There is nothing about the jury's verdict in this case that resembles an improper compromise. After a trial spanning more than five weeks, the jury deliberated for two days and delivered a unanimous verdict of liability against Janssen, awarding damages that were less than Relators sought and more than the zero dollars Janssen lobbied for. Rather, the verdict is the product of an active jury performing its sworn duty.

Finally, Janssen reprises the arguments from its Rule 50(b) motion regarding the jury's purported inability to find the number of false claims and damages other

[22] *See also Stanton by Brooks v. Astra Pharma. Prods., Inc.*, 718 F.2d 553, 576–77 (3d Cir. 1983) (ordering new trial on all issues where the jury's award was smaller than reported verdicts for similar injuries to similarly situated plaintiffs and far smaller than the evidence might have supported).

than the full amount of what Relator's expert Prof. Shaked attested to. Def. Br. at 39–42;[23] *see* Def. Br. Rule 50(b) at 46–49. Those arguments are meritless, as Relators explained in their opposition to the Rule 50(b) motion. Rel. Br. Rule 50(b) at 60–68. The Court should deny Janssen's Motion for New Trial on this ground for the same reasons.

C. The jury properly determined the number of false claims.

Finally, Janssen argues that the jury's award is "improper" because the number of false claims the jury found "is not segregated by type of claim (state or federal) or payor (Medicare, Medicaid and ADAP)." Def. Br. at 42. These arguments are incorrect and should be rejected.

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[23] Janssen also attempts to manufacture jury "confusion" regarding its request for guidance locating certain testimony relating to federal and state claims. Def. Br. at 41. The Court correctly referred the jury to "the evidence presented"—which included testimony from Prof. Shaked, testimony regarding Dr. Jena's purported "corrections" to Prof. Shaked's damages calculations broken out by Medicare, Medicaid, and ADAP for each of the four OL promotions of Prezista and Intelence, the claims data presented by Ian Dew, and Janssen's own documents with payor-by-payor breakouts for Prezista and Intelence. *See* Rel. Br. Rule 50(b) at 63. The jury had all this evidence available to review, and its own recollection of the testimony in the entire record, and returned with a verdict after the Court's instruction. Janssen's baseless and speculative claims of jury "confusion" are not grounds for overturning the verdict. *See Montgomery Cty. v. Microvote Corp.*, No. 97-6331, 2001 WL 722150, at *8 (E.D. Pa. Jun. 25, 2001) (denying motion for a new trial after rejecting the argument that the jurors asking two questions indicated that they were confused); *see also Total Containment, Inc. v. Dayco Prods., Inc.*, No. 97-6013, 2001 WL 984708, at *12 (E.D. Pa. May 3, 2001) ("a court may not inquire into the internal workings of the jury's decisional processes on the mere suspicion of confusion.") (citations and internal quotations omitted).

First, Janssen's argument commingles the jury's findings of damages to the United States and damages to the States with its findings of the number of false claims under the federal FCA. The jury found in Question One that Janssen "violated the *federal* False Claims Act" by "unlawfully promoting Prezista or Intelence." *See* Dkt. 435 at 3 (Verdict Form) (emphasis added). It then found, in Question Three, the damages to *the United States* as a result of its liability findings under the federal FCA in Question One.

Separately, the jury found in Question Seven that Janssen "violated the States' False Claims Acts" by "unlawfully promoting Prezista or Intelence." *Id*. at 5-6. The Court's instructions with regard to Janssen's liability under the States' FCAs specifically and *only* pertained to *Medicaid*. *See* Final Jury Instructions, Instruction No. 23 ("State Law Claims"). The jury then found damages to *the States*—pertaining to Medicaid—in Question Eight.[24] There is no basis for Janssen to argue that "the jury's finding of $120,004,736 in federal damages constitutes an unknown

[24] CMS requires that any claims brought on behalf of state Medicaid programs must seek the entirety of the damages incurred by the program and then remit the federal portion to CMS *after recovery*. *See* CMS Letter to State Health Officials, SHO #08-004 (October 28, 2008), available at https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/sho08004.pdf (addressing state recovery of damages for Medicaid programs under state False Claims Acts) ("Any State action taken as a result of harm to a State's Medicaid program must seek to recover damages sustained by the Medicaid program *as a whole*, including both Federal and State shares . . . . States are also required to return the FMAP percentage on *State recoveries* based upon actions brought against third parties, such as actions against pharmaceutical companies, alleging inappropriate Medicaid expenditures.") (emphasis added).

combination of dollars" paid by Medicare, Medicaid, and ADAP.[25] Def. Br. at 44; *see* Rel. Br. Rule 50(b) at 67–68.

With respect to the *number of false claims*, the jury found that Janssen "caused to be submitted" 159,574 false claims as a result of "any False Claims Act violations" it found in *Question One* under the *federal* False Claims Act. *Id.* at 3. There is thus no basis for Janssen to complain that the jury's finding of "159,574 false claims constitutes an unknown combination of claims made to federal *and* state payors." Def. Br. at 44.

The jury's verdict does precisely what is required. It finds damages sustained by the United States (for Medicare or ADAP) and the States (for Medicaid),[26] and

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[25] In accordance with the verdict form, Relators specifically argued to the jury that damages for Medicare or ADAP claims should be allocated to the *United States* in Question Three and damages for state Medicaid claims should be allocated to the *States* in Question Eight. *See* 6/11/24 Tr. 8020:6–13 ("What amount of damages, if any, did Relators prove by a preponderance of the evidence, it's more likely than not, that the United States, the federal government, suffered as a result of that conduct that you found in that question? That's the reduced damages amount. That's *only for Medicare and ADAP*, the AIDS Drug Assistance Program, *federal funding*. 300,377,000 is what we're asking you to return to the government.") (referring to Question Three) (emphasis added), 8023–06-10 ("What amount of damages, if any, did Relators prove by a preponderance of the evidence that the *states* sustained as a result of any violations you found in that question?" . . . 61,523,000 back to *Medicaid*.") (referring to Question Eight) (emphasis added).

[26] CMS requires that any claims brought on behalf of state Medicaid programs must seek the entirety of the damages incurred by the program and then remit the federal portion to CMS *after recovery*. *See* CMS Letter to State Health Officials, SHO #08-004 (October 28, 2008), available at https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/sho08004.pdf (addressing state recovery of damages for Medicaid programs under state False Claims Acts) ("Any State action taken as a

separately finds the number of false claims submitted as a result of Janssen's violations of the federal FCA for the Court's assessment of penalties. Nothing else was necessary, and Janssen's motion for a new trial as to damages and the number of false claims fails.

CONCLUSION

Janssen's Motion for a New Trial should be denied in its entirety.

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result of harm to a State's Medicaid program must seek to recover damages sustained by the Medicaid program *as a whole*, including both Federal and State shares . . . . States are also required to return the FMAP percentage on *State recoveries* based upon actions brought against third parties, such as actions against pharmaceutical companies, alleging inappropriate Medicaid expenditures.") (emphasis added).

Dated: October 18, 2024

Respectfully Submitted,

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